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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,580	02/15/2001	Lawrence E. Cornett	023533-0113	4347

22428 7590 05/22/2003

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
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PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/783,580

Applicant(s)

Cornett et al.

Examiner

Scott D. Priebe, Ph.D.

Art Unit

1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED May 15, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s):  
first rej. under 112, 1st para. (cl. 14, 44-48, 50); rej. under 112, 2nd para., all under 102 & 103
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see next page
6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: none
- Claim(s) objected to: none
- Claim(s) rejected: 1-5, 8-31, 33-35, 38, and 44-57
- Claim(s) withdrawn from consideration: none
8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

SCOTT D. PRIEBE, PH.D.  
PRIMARY EXAMINER  
ART UNIT 1632

Art Unit: 1632

**Advisory Action**

Item 5:

With respect to the rejection of claims 13, 14, 44-48 and 50 for inadequate written description, Applicant repeats arguments previously made, which have already been addressed. Applicant's comments concerning the newly presented Stripp and McGraw references are moot, these exhibits were not considered (see item 6). Applicant points out that the alpha actin promoter and McGraw (1999) (Exh. 7 filed 11/7/02) was mentioned in the specification at page 10, lines 22-24. However, this part of the specification is directed to a discussion of prior art, and does not indicate that the alpha actin promoter was either an smooth muscle cell promoter nor that it was to be used within the context of the invention. Applicant states that DNA sequences of many mammalian cell specific promoters have been described. However, the only such promoters which are at issue are epithelial cell specific promoters and smooth muscle cell specific promoters, and whether a genus of such promoters were possessed by Applicant. The final rejection explained why Applicant's evidence was insufficient. With respect to the oft-quoted citation from *Hybritech v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (CA FC 1986), the court has clarified this position. It is true that a specification need not disclose what is well known in the art. However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. The rule that a specification need not disclose that which is well known in the art simply means that omission of minor details does not cause a specification to fail the enablement requirement, and is not a substitute for an

Art Unit: 1632

enabling disclosure. However, if there is no disclosure of starting materials and of conditions under which the process can be carried out, undue experimentation is required. Failure to provide such teachings can not be rectified by asserting that the disclosure of the missing necessary information was well known in the prior art. See *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 101, 1005 (CA FC, 1997). For embodiments of the invention requiring the recited promoters, these promoters are critical to the invention, and failure to describe them is not “a minor omission,” particularly since Applicant has provided evidence of only a single promoter for each recited class known at the time the instant invention was made.

With respect to the rejection of claims 1-5, 8-38, 44-50 for lack of enablement, no new arguments are presented here. Applicant has still failed to address the known issues in this art as disclosed in Orkin, Factor, and Demoly; for example, that reporter gene studies are not predictive of therapeutic success, that asthmatic lung presents unsolved impediments to vectors delivery and was deemed highly unpredictable both before and after the time the instant invention was made.

In the second to last paragraph of page 8, Applicant alludes to an “attached declaration.” No declaration was received with the response filed 5/15/03, and it is unclear whether or not this declaration is the one previously provided as Exh. 8, filed 11/7/02.

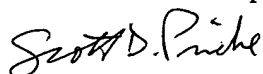
Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The

Art Unit: 1632

faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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Technology Center 1600  
Art Unit 1632